REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application are respectfully requested in light of the amendments above and the comments which follow.

As correctly noted in the Office Action Summary, claims 1-40 were pending. By the present response, claims 1 and 3-5 have been amended, claims 17-22 canceled, and claims 41-46 added. Claims 23-40 are withdrawn. Thus, upon entry of the present response, claims 1-16 and 41-46 are pending and await further consideration on the merits.

Support for the foregoing amendments can be found, for example, in at least the following locations in the original disclosure: paragraphs [0040], [0042], [0063], [0073] and the original claims.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

Claims 1-14 and 16-22 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,702,716 to Dunn et al. (hereafter "*Dunn et al.*") on the grounds set forth on page 2 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

The present invention is directed to an implant that can easily and quickly be shaped *in-situ* or *ex-situ* into a desired form, and that can promote the end-growth and generation of bone tissue.

A moldable implant composition formed according to the principles of the present invention is set forth in amended claim 1. Amended claim 1 recites:

> *1. A moldable implant composition for use in repairing a bone defect in a living organism, comprising:*

> *a plurality of biocompatible synthetic non-polymeric granules;*
> *a biocompatible polymer on at least a portion of said granules so as to form an implant mass comprising said granules and said biocompatible polymer; and*
> *a plasticizer in said implant mass in an amount sufficient to condition at least a portion of said biocompatible polymer so that said implant mass is initially plastically deformable into a desired shape and then hardenable upon removal of at least a portion of said plasticizer from said implant mass.*

Dunn et al. is directed to a system for controlled release of biologically active materials and to a liquid composition for its formation. The material described therein is taught as being a polymer system in the form of a combination of liquid compositions and an aqueous medium that coagulates the composition into a solid microporous polymeric matrix. See, e.g., column 3, lines 58-60. *Dunn et al.* further teaches that the liquid polymer system disclosed therein may include a "bioactive material." In this regard, the bioactive material can either be miscible in the polymer to provide a homogeneous mixture with the polymer component, or insoluble in polymer to form a suspension or dispersion with the polymer (see, e.g., column 11, lines 21-24). Thus, as taught by *Dunn et al.*:

> Upon formation of the polymer system from the liquid composition, the biologically active material becomes incorporated into the polymer matrix. (column 11, lines 25-27)

Dunn et al. discloses that one such bioactive material is tricalcium phosphate (see, e.g., column 11, lines 8-9).

However, *Dunn et al.* fails to anticipate the moldable implant composition recited in claim 1.

As readily apparent from the above, claim 1 requires that the moldable implant composition of the present invention include a plurality of biocompatible

synthetic non-polymeric granules. By contrast, nowhere does *Dunn et al.* disclose that the bioactive material which may be included in the polymer system be in the form of granules. *Dunn et al.* clearly fails to anticipate at least this aspect of the presently claimed invention. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

The remaining claims depend from claim 1. Thus, these claims are also distinguishable over *Dunn et al.* for at least the same reasons set forth above.

Claims 1-14 and 16-22 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,294,187 to Boyce et al. (hereafter "*Boyce et al. '187*") on the grounds set forth on page 3 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

Boyce et al. '187 is directed to a load bearing osteoimplant comprising shaped compressed bone particles in combination with one or more biocompatible components. *Boyce et al. '187* disclsoes that the bone particles employed in the implant composition described therein can be obtained from cortical, canceloous and/or corticocancellous bone (see, e.g., column 4, lines 40-42).

However, as readily apparent from the above, claim 1 requires a moldable implant composition comprising a plurality of biocompatible synthetic non-polymeric granules. The bone particles described by *Boyce et al. '187* are not synthetic materials. Thus, *Boyce et al. '187* fails to anticipate at least this aspect of amended claim 1. Reconsideration and withdrawal of the rejection is respectfully requested.

The remaining claims depend from claim 1. Thus, these claims are also distinguishable over *Boyce et al. '187* for at least the same reasons noted above.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

Claim 15 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,294,187 to *Boyce et al. '187* in view of U.S. Patent No. 6,332,779 to Boyce et al. (hereafter "*Boyce et al. '779*")on the grounds set forth on page 3 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

As explained above, *Boyce et al. '187* fails to disclose a composition which includes granules formed from synthetic material as required by amended claim 1. In addition, as acknowledged on page 3 of the Official Action, *Boyce et al. '187* also fails to disclose a membrane on the surface of an implant mass.

Boyce et al. '779 is cited as allegedly teaching providing a membrane over bone graft material. However, even if the teachings of *Boyce et al. '187* and *Boyce et al. '779* were combinable in the manner suggested, the claimed invention would not result. Namely, *Boyce et al. '779*, like *Boyce et al. '187,* discloses an osteoimplant which contains natural bone particles as a main constituent component (see, e.g., column 3, lines 42-45). Thus, *Boyce et al. '779* fails to cure the deficiencies previously noted above in connection with the teachings of *Boyce et al. '187*. More specifically, *Boyce et al. '779* also fails to disclose a composition which includes granules formed from a synthetic material as required by amended claim 1. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

NEW CLAIMS

By the present response, claims 41-46 have been added. Independent claims 40 and 43, like amended claim 1, require the presence of biocompatible synthetic

non-polymeric granules. Thus, newly presented claims 41 and 43, and those claims depending thereon, are distinguishable over the applied prior art for at least the same reasons noted above.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is earnestly solicited. Should the Examiner feel that any issues remain, it is requested that the undersigned be contacted so that any such issues may be adequately addressed and prosecution of the instant application expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: January 18, 2008 By: Scott W. Cummings
Registration No. 41,567

P.O. Box 1404
Alexandria, VA 22313-1404
703 836 6620